AUG 2 6 2004

K041661

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Elizabeth J. Mason Sr. Regulatory Affairs Specialist
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Telephone:	(714) 282-4800, ext. 7830
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Date of Submission:	June 16, 2004
Classification Name:	Endosseous Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	Nobel Biocare Endosseous Implants
Legally Marketed Device(s):	Replace HA Coated Implants (K022424) Brånemark System Implants (K022562) Replace TiUnite Endosseous Implants (K023113)

Device Description:
Nobel Biocare Endosseous Implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore chewing function to partially or fully edentulous patients.

Nobel Biocare Endosseous Implants are machined from titanium and available straight or tapered. The implants are either a) coated with hydroxyapatite powder, i.e. HA coated implants; b) have a surface treatment of the implant that consists of a titanium oxide layer, i.e. TiUnite implants; or c) do not have any coating or surface treatment, i.e. Brånemark implants.

Nobel Biocare Endosseous Implants may be placed in the oral cavity using either a single stage surgical procedure or a two stage surgical procedure. If a single stage procedure is used, the implants may be immediately loaded following insertion. Nobel Biocare Endosseous Implants can be placed anywhere in the upper or lower jaw where good initial stability of the implant can be obtained.

Indications for Use:
Nobel Biocare Endosseous Implants are indicated for use as root form endosseous implants in partially or fully edentulous patients for the purpose of restoring chewing function. Implants may be tilted up to 45°. When used with angulations between 30° and 45°, tilted implants must be splinted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Elizabeth J. Mason
Senior Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K041661
Trade/Device Name: Nobel Biocare Endosseous Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: June 16, 2004
Received: June 22, 2004

Dear Ms. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use

510(k) Number (if known): K041661

Device Name: Nobel Biocare Endosseous Implants

Indications For Use:

Nobel Biocare Endosseous Implants are indicated for use as root form endosseous implants in partially or fully edentulous patients for the purpose of restoring chewing function. Implants may be tilted up to 45°. When used with angulations between 30° and 45°, the following applies:

- the tilted implants must be splinted
- a minium of four implants must be used when supporting a fixed prosthesis in a fully edentulous arch

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K041661